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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,928	03/28/2001	George H. Scherr		4270

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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/818,928	SCHERR, GEORGE H.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *78-107* is/are pending in the application.

4a) Of the above claim(s) *93-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *78-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed May 25, 2007. All previous rejections have been withdrawn unless stated below.

Response to Declaration and Affidavit Under 37 C.F.R. 1.132

The Declaration under 37 CFR 1.132 filed May 25, 2007 is insufficient to overcome the rejection of claims 78-107 based upon 35 USC 112 as set forth in the last Office action because: The Applicant does not assert any arguments or data.

Claims

Claim Rejections - 35 USC § 112 – Indefiniteness (Previous Rejections)

Claims 78-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejections are maintained.

1) Claims 78-85 and 87-92 recite "suitable medicinal agent". The term "suitable" in claim 78 is a relative term, which renders the claim indefinite. This rejection is maintained.

Applicant argues that one of skill in the art would not use a medicinal agent that would interfere with the healing of the tissue. No one skilled in the art would be foolish enough to include a medicinal agent that is totally unrelated to the purpose for which the instant invention is intended, treatment of wounds. Applicant finds exception with the

Examiner's assertion that the incorporation of "suitable" is too vague in defining the medicinal agent that may be incorporated into a medicinal dressing for treatment of wounds. This argument is not persuasive.

Applicant is correct in their assertion that one skilled in the art would not use an inappropriate medicinal agent to treat wounds with the disclosed invention. The Examiner takes the position that the term "suitable" is indefinite because the term "medicinal agent" is a definite term that does not need further description by the term "suitable" because it is established by the claims what the purpose of the "medicinal agent" is. That being said the incorporation of the term "suitable" is unnecessary because one skilled in the art would be able to determine the appropriate medicinal agent with the recitation of "medicinal agent" alone.

2) Claim 82 recites the limitation "said water soluble acid " in the first line of the claim. The rejection is maintained.

Applicant argues that the acid is disclosed in the acid is disclosed in the claims and that it is a water soluble acid because the compositions are in an aqueous solution. This argument is not persuasive.

Applicant uses the term "said water soluble acid". The independent claim recites "aqueous soluble acid" but does not recite "water-soluble acid" therefore there is no "said water-soluble acid" in the independent claim because this implies that the term "water soluble acid" was used previously. It is suggested Applicant replace the term "water" with "aqueous".

3) Claim 86 recites the limitation "said medicament" in the first line. There is insufficient antecedent basis for this limitation in the claim.

Applicant argues there is sufficient antecedent basis for the term "medicament" because the specification sets forth groups of medicaments that may be used in the instant invention. This argument is not persuasive.

Applicant uses the term "medicament". The independent claim recites "medicinal agent" but does not recite "medicament" therefore there is no "said medicament" in the independent claim because this implies that the term "medicament" was used previously. It is suggested Applicant replace the term "medicament" with "medicinal agent".

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 78-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al. (US 5,089,606) in view of Nelson (US 4,065,614), Park et al. (US 2001/0038831), Pellico (US 4,291,025) and Shah et al. (US 5,527,271).

Cole et al. disclose insoluble hydrogel foam wound dressings. The insoluble hydrogel is made by using a divalent or trivalent salt to render a polysaccharide insoluble. Suitable polysaccharides are alginic, pectic and hyaluronic acids (col. 6, lines 1-9). The salts used to render the polysaccharides insoluble are calcium salts including calcium sulphate and calcium chloride, encompassing claims 84-85 and 89-90. The effervescent compound includes an alkali metal carbonate and bicarbonate; encompassing claims 79-81. The acids used to react with the effervescent compounds are water-soluble acids including acetic, lactic, malic and gluconic acids (col. 6, lines 23-52). The dressings are made by mixing two components to form a final mixture. Component A comprises a polysaccharide, sodium carbonate, and water. Component B comprises a polysaccharide, water and acetic acid. When A and B are combined they form a foam (col. 5, lines 54-65). The medicaments used in the compositions include antimicrobials and anti-inflammatory agents. The medicaments are preferably used with detergent polymers, surfactants (col. 7, lines 1-33). The medicament is incorporated into component B (see Examples). The reference differs from the instant claims insofar as it does not disclose the preferred polysaccharide to be pectic acid; the addition of

ammonium hydroxide, surfactants, plasticizers and sodium tetraborate; and that the composition is poured on a fibrous cloth.

Nelson discloses reacting pectin with ammonium hydroxide to gain rapid conversion of ester groups to amide in the pectin to produce low methoxyl (LM) pectin (col. 6). Low methoxyl pectin is typically obtained through a chemical de-esterification process and has a degree of methylation of less than 50%. LM pectins react with calcium to form gels (col. 1, lines 38-58). Pectin is available commercially as high ester pectins (col. 3, lines 37-40). The reference differs from the instant claims insofar as it does not disclose the pectins are used in a sponge or foam for a wound dressing or a process for making the wound dressing.

Park et al. discloses methods of making hydrogel foams. The foams are made from monomers, a cross-linker, a foaming agent, an initiator and a foam stabilizer (paragraph 0067). The compositions use surfactants as foam stabilizers in order to stabilize the foam until gelling occurs. The surfactants include Tween and Span surfactants as well as polyoxyethylene-polyoxypropylene block copolymers, encompassing claim 88. The reference differs from the instant claims insofar as it does not disclose the preferred polysaccharide to be pectic acid; the addition of ammonium hydroxide, plasticizers and sodium tetraborate; and that the composition is poured on a fibrous cloth.

Pellico discloses agar gel topical dressings to apply on wounds. The compositions may comprise plasticizers to impart high strength yieldability to the gel and absorb fluids from the wound. Gel strengthening agents include sodium borate to

impart added toughness to the gel dressing. The gels may also comprise antibacterials, vitamins, amino acids, humectants and antibiotics (col. 3, line 30 to col. 4, line 5). It was also disclosed by the reference that glycerin might also be used in wound preparations (col. 2, line 8). The reference differs from the instant claims insofar as it does not disclose a procedure for making a insoluble pectin sponge or foam comprising adding ammonium hydroxide, an effervescent compound, and acid followed by pouring the solution onto a fibrous cloth and drying the composition.

Shah et al. disclose wound dressings comprising a hydrogel polymer impregnated into a substrate. The substrate materials include cotton gauze (see Abstract). Generally, the greater the amount of the hydrogel polymer impregnated, the greater the absorption capability of the wound dressing and the longer the wound dressing may be retained on the wound. The hydrogel solution is made and is applied to the substrate in any manner capable of uniformly impregnating the substrate and then dried (col. 4, lines 25-55). The reference differs from the instant claims insofar as it does not disclose the hydrogel is a insoluble pectin sponge or foam using a metal ion salt, acid, an effervescent agent, ammonium hydroxide and sodium tetraborate.

It would have been obvious to one of ordinary skill in the art to have used the pectins having an LM of less than 50% and incorporated ammonium hydroxide into the pectin solution to make insoluble pectin foams and sponges of the primary reference motivated by the desire to use a pectin that was reactive to calcium to make the pectin insoluble and to make commercial pectin suitable for use by de-esterification, as disclosed by Nelson et al.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. *See Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., *In re Linder*, 457 F.2d 506, 507 (CCPA 1972); see also *In re Dial*, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to use the surfactants, plasticizers and sodium tetraborate to make the compositions of the primary reference motivated by the desire to obtain the gel strengthening function of the plasticizers and the sodium tetra borate and the foam stabilizing effect of the surfactants, as disclosed by the secondary references of Park et al. and Pellico.

It would also have been obvious to one of ordinary skill in the art to have poured the gel compositions of the primary reference onto a cotton gauze motivated by the desire to give the wound dressing greater absorption capability and to retain the wound dressing on the wound for a longer period of time as disclosed by Shah.

2) Claims 91-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al. (US 5,089,606) in view of Nelson (US 4,065,614), Park et al. (US 2001/0038831), Pellico (US 4,291,025 and Shah et al. (US 5,527,271) as applied to claims 78-90 above, and further in view of Bannert (US 5,147,648).

The primary and secondary references are discussed above. The references differ from the instant claims insofar as they do not disclose that mixtures of polysaccharides are used to make the gel compositions.

Bannert discloses the advantage of using a mixture of polysaccharides. A mixture of polysaccharides has increased adhesiveness when reacted with a metallic salt. The disclosed compositions may comprise a mixture of alginate and pectin. Pectins with a low degree of esterification are preferable. A calcium salt is added to the polysaccharides to form the gels. Glycerine is added to increase the flexibility of the gels. Tensides are added to improve wetting. Preservatives are also added to the gels. The gels formed in accordance with the invention under discussion can be used to keep the mucosa moist or to protect it. Additionally when a disinfectant and/or drugs are added to the gel, the gel can then be used in treating diseases that affect the mucosa. The reference differs from the instant claims insofar as it does not disclose the compositions are made in to a foam wound dressing by adding acid, an effervescent compound, ammonium hydroxide and tetraborate or the compositions are poured on a fibrous cloth.

It would have been obvious to one of ordinary skill in the art to have mixed polysaccharides in the procedure of the combined primary and secondary references motivated by the desire to make a wound dressing with increased adhesiveness, as disclosed by the tertiary reference.

Obvious-Type Double Patenting (New Rejection)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 78-92 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,696,077 in view of Cole et al. (US 5,089,606). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are coextensive insofar as they disclose similar methods of making an insoluble foam. The patented claims differ from the instant claims insofar as they disclose an alginate as the sponge where as the instant claims disclose pectin.

Cole et al. disclose insoluble hydrogel wound dressings comprising a polysaccharide. The polysaccharide may be pectin, hyaluronic acids or alginate. The reference differs from the instant claims insofar as it does not disclose a process for making an insoluble pectin sponge.

It would have been obvious to one of ordinary skill in the art to have used pectin in place of alginate motivated by the desire to use a compound with similar properties that could perform the same function as disclosed by the secondary reference.

2) Claims 78-92 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 7,128,929 in view of Cole et al. (US 5,089,606). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are coextensive insofar as they disclose similar methods of making an insoluble foam. The patented claims differ from the instant claims insofar as they disclose an alginate as the sponge where as the instant claims disclose pectin.

Cole et al. disclose insoluble hydrogel wound dressings comprising a polysaccharide. The polysaccharide may be pectin, hyaluronic acids or alginate. The reference differs from the instant claims insofar as it does not disclose a process for making an insoluble pectin sponge.

It would have been obvious to one of ordinary skill in the art to have used pectin in place of alginate motivated by the desire to use a compound with similar properties that could perform the same function as disclosed by the secondary reference.

Claims 78-92 are rejected.

Claims 93-107 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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